DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

Via Federal Express 4165 0459 5687

Our Reference: 2916339

September 15, 2000

Mr. Andy Bresler, President
Manna Pro Corporation
707 Spirit 40 Park Drive
Suite 150
St. Louis, Missouri 63005

WARNING LETTER

Dear Mr. Bresler:

An inspection of your medicated feed manufacturing facility, Manna Pro Corporation, l 2962 South Cedar Avenue, Fresno, California, 93725, on July 27 through August 8, 2000, by Food and Drug Administration (FDA) Investigator John A. Gonzalez, revealed significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds (Title 21 Code of Federal Regulations (CFR), Part 225 - 21 CFR 225). Such deviations cause the medicated feeds manufactured at your mill to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). The following deviations were observed:

Our investigation found that you failed to investigate the reasons for failed feeds, you did not implement corrective action, and you did not discontinue distribution of feeds that failed to meet their labeled drug potencies until it was determined that proper control procedures had been established. You also failed to follow your written procedures for "out-of-control assays."

You failed to sequence, flush, or otherwise physically clean your manufacturing and delivery equipment between batches of medicated feed to prevent cross-contamination.

You failed to maintain a complete Master Record File (master labels were not dated and signed or initialed by a qualified person). Your Master Record File also lacked assay

requirements. Production records lacked a written endorsement in the form of a signature or initials by a responsible person. A responsible person failed to check batch production records at the end of the working day in which the product was made to determine whether all required production steps had been performed. Each batch or production run of medicated feeds was not applied to the label, package, invoice or shipping document permitting the tracing of the complete and accurate manufacturing history.

You failed to identify distribution records or labels with a lot or control number, date of manufacture or other suitable identification for each shipment. This information permits you to relate complaints to specific batches or production runs and may be helpful in instituting a recall.

Complaint records did not document the address of the complainant and the lot or control number or date of manufacture of the medicated feed involved. The complaint did not include all correspondence and a description of all investigations made, as well as the method of disposition.

You failed to proofread labeling received from the printer against the Master Record File to verify its suitability and accuracy. The proofread label was not dated, initialed by a responsible individual, and kept for one year after all the labels from that batch had been used.

You failed to visually examine incoming shipments of drugs for identity and damage. Your receipt records did not list the condition of the drug when received, and the return of any damaged drugs. You failed to determine the quantity of drugs on hand at the beginning and end of the workday. You failed to account for the amount of each drug used. You failed to take action to reconcile any discrepancies in the daily inventory record. You failed to make a daily comparison of the actual amount of drug used with the theoretical usage. Significant discrepancies were not investigated and you did not take corrective action. Any medicated feeds remaining on the premises that were affected by these discrepancies were not detained until the discrepancies were reconciled.

You failed to develop and implement procedures to monitor the capability of equipment to produce homogeneous medicated feeds of intended potency.

You failed to adequately train and supervise employees, and you did not provide them with an on-going program of evaluation and supervision.

Your building grounds were not routinely maintained so that they were free of improperly stored equipment. Building grounds were not of suitable construction to minimize access by rodents, insects and other pests.

Causing the adulteration of drugs after receipt in interstate commerce, and delivering for introduction into interstate commerce of any article in violation of Section 501 are violations of Section 301(k) and 301(a) of the Act, respectively.

You should take prompt action to correct these CGMP violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these CGMP violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure, injunction, and/or notice of opportunity for a hearing on a proposal to withdraw approval of your Medicated Feed Mill License per Section 512(m)(4)(B)(ii) of the Act and 21 CFR 514.115(c)(2). (This letter constitutes official notification under the law.) Based on the results of the July 27, through August 8, 2000, inspection, evaluated together with the evidence before FDA when the Medicated Feed Mill License was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feeds are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs therein. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

Until the CGMP violations have been corrected and the corrections verified by FDA, the Center for Veterinary Medicine will not approve medicated feed applications for your facility.

We sent you a previous Warning Letter dated March 18, 1997. That letter charged your failure to maintain a drug inventory system showing the beginning and ending quantity of drugs on hand each day, your failure to make a daily comparison between actual amounts of drugs used and theoretical drug usage, your failure to date and initial the proofread label upon receipt from the printer, your failure to endorse production records in writing by a responsible person, and your failure to perform scheduled assays on all manufactured feeds.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act are being met. You have failed to take adequate corrective action. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen (15) days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation

demonstrating that corrections have been made. Please direct your reply to John A. Gonzalez, CSO, 2202 Monterey Avenue, Suite 104E, Fresno, California, 93721.

Sincerely yours,

Kris A. Foster
Acting Director
San Francisco District

cc: Mr. Louis D. Hampton
Plant Manager
Manna Pro Corporation
2962 South Cedar Avenue
Fresno, California 93275